A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 7, 2008 has been entered.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/555,038 in view of Cham et al (U.S. Patent No. 5,958,770) and Schmidt et al (U.S. Patent No. 6,242,583). The present claims are directed to a glucose-solasodine conjugates having protective groups on the glucose moiety and methods for their preparation. The claims of the copending application are directed to

galactose-solasodine conjugates having protective groups on the galactose moiety and methods for their preparation. Since Cham et al disclose glucose or galactose conjugates of solasodine (columns 3 and 4) and Schmidt et al disclose various protective groups well known in sugar synthesis (column 20, lines 37-45), the substitution of protective galactose for protected glucose in the claimed compounds and methods would have been prima facie obvious to a person having ordinary kill in the art at the time the claimed invention was made

This is a provisional obviousness-type double patenting rejection.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Since a terminal disclaimer has not been filed at the time of the present office action, the above stated provisional rejection has not been overcome.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (U.S. Patent No. 5,958,770) in view of Schmidt et al (U.S. Patent No. 6,242,583).

Cham et al disclose glucose conjugate of solasodine, wherein the hydroxyl groups are substituted by acetyl (column 3 and column 4, lines 1-22) but do not disclose glucose-solasodine conjugates wherein the glucose moiety is substituted by benzoyl or a pivaloyl group. However, since Schmidt et al teach the conventional use of acetyl,

benzoyl and pivaloyl groups in sugar synthesis (column 20, lines 37-45), a person having ordinary skill in the art at the time the present invention was made would have been motivated to substitute benzoyl group or pivaloyl group for the acetyl group on the compound disclosed by Cham et al because the results achieved from such a substitution would have been expected.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant contends that Cham refers to solasonine or solamargine derivatives that play a role in control of cellular function and does not refer to glucose-solasodine conjugates as intermediates in solamargine or solasonine synthesis. This argument has not been found persuasive. Cham et al disclose in columns 3-4 a broad genus. Some of the species within said genus are naturally occurring compounds, while others are not. Therefore, a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to synthesize the non-naturally compounds disclosed by Cham et al using intermediates encompassed by claim, which reds on a naturally occurring compound substituted with conventional protecting groups.

Claims 2 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (U.S. Patent No. 5,958,770) in view of Holick (U.S. Patent No. 5,612,317) and Scmidt et al (U.S. Patent No. 6,242,583).

Cham et al disclose glucose conjugates of solasodine (columns 3-4) but do not disclose a process for preparing said compounds by reacting solasodine with a protected glucopyranosyl donor. However, since Holick teaches a conventional method

for glycosylating a closely analogous steroid derivative by reacting a steroid with a protected sugar donor (Fig. 3 and Example 1) and Schmidt et al disclose the conventional use of acetyl, benzoyl and pivaloyl protecting groups in sugar synthesis (column 20, lines 37-45), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to prepare the compounds disclosed by Cham et al using the method disclosed by Holick and conventional protecting groups disclosed by Schmidt et al because such a person would have expected to prepare the glucose-solasodine conjugates.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant contends that Cham et al, Schmidt et al and Holick do not refer to the specific D-glucopyranosyl donors encompassed by the present process claims. This argument has not been found persuasive since the claims still read on a conventional glycosylation process disclosed Hollik using conventional protecting groups disclosed by Schmidt in order to prepare compounds disclosed by Cham et al.

Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (U.S. Patent No. 5,958,770) in view of Ohira et al (U.S. Patent No. 6,084,081).

Cham et al disclose solamargine and glucose-solasodine conjugate (columns 3-4) but do not sisclose a method of preparing solamargine from glucose-solasodine conjugate. However, since glycosylation of a sugar moiety was well known in the art at the time the present invention was made as disclosed by Ohira et al (see, for example,

columns 19-20 and column 21, lines 1-8), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to prepare the compounds disclosed by Cham et al using the conventional method disclosed by Ohira et al.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant contends that neither Cham et al disclose compounds that play a role in control of cellular function and does not refer to said compound as intermediates. This argument has not been found persuasive because a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to use conventional synthesis process to prepare compounds disclosed by Cham et al wherein said compounds are not naturally occurring.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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